



EUROPEAN  
COMMISSION

Brussels, **XXX**  
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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid in the Union list of flavourings**

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13<sup>1</sup>, and in particular Articles 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings<sup>2</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012<sup>3</sup> adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.
- (4) On 24th February 2015, an application was submitted to the Commission for authorisation of the use of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid, FL No: 16.130, as a flavouring substance. The application was notified to the European Food Safety Authority (the Authority) for its opinion. The application was also made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

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<sup>1</sup> OJ L 354, 31.12.2008, p. 34.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

- (5) The Authority evaluated the safety of this substance FL No: 16.130 when used as a flavouring substance<sup>4</sup> and concluded that its use does not give rise to safety concerns at the estimated levels of dietary intake. The Authority also noted that this substance is intended to be used as a substance with flavouring modifying properties. The conditions of use of this substance should therefore reflect this fact. Based on this, restrictions of use for certain foods in certain food categories should be introduced.
- (6) The Union list referred to in Regulation (EC) No 1334/2008 is intended to regulate only the use of flavouring substances which are added to food in order to impart or modify odour and/or taste. Substance FL No: 16.130 could also be added to food for other purposes than flavouring and such uses remain subject to other rules. This Regulation lays down conditions of use which relate solely to the use of FL No: 16.130 as a flavouring substance.
- (7) Taking into account that according to the application only this substance 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid, FL No: 16.130, and its hemisulfate salt, and not other salts of this acid, are intended to be added to food, the restrictions of use laid down are only applicable to this acid and only its hemisulfate salt. Note 1 of section 2 of Annex I regarding applicability of the restrictions of use to other salts when an acid is authorised is not applicable in this case.
- (8) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Part A of Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

The restrictions of use laid down for this substance 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid, FL No: 16.130 are only applicable to this acid and the hemisulfate salt and not to other salts of this acid. Note 1 of section 2 of Annex I of Regulation (EC) No 1334/2008 regarding applicability of the restrictions of use to other salts when an acid is authorised is not applicable in this case.

#### *Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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<sup>4</sup> EFSA Journal 2017;15(1):4660.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*